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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/736,051

12/13/2000

Hua Zhu Ke

PC9344BRTR

6748

7590

04/21/2005

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EXAMINER

LEARY, LOUISE N

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 04/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/736,051

Applicant(s)

KE ET AL.

Examiner

Louise N. Leary

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 15 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69 and 72 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 8-9, 11-12, 30, 33, 46-47, 49-50, 52, 54-55, 57, 62, 65 is/are rejected.
- 7) ☒ Claim(s) 7, 10, 13, 14, 16-29, 48 and 53 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All - b) ☐ Some - c) ☐ None of: \_\_\_\_\_
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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1. Claims 1-4, 6-14, 16-30, 33-42, 45-50, 52-55, 57-62, 65-69, and 72 are pending in this application.

Claims 5, 15, 31-32, 43-44, 51, 56, 63-64, 70-71, and 73-108 have been canceled per applicant's request.

2. The rejection of claims 73-75, 79-80, 84-89 and 92-108 under 35 USC 102(a) or in the alternative as being unpatentable over Carpino et al (US 6,110,932 patented August 29, 2000 with priority claim to Provisional Application No. 60/009,469 filed 12/28/95) is moot due to cancellation of said claims in applicant's amendment filed March 15, 2005.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6, 8-9, 11-12, 30, 33, 46-50, 52, 54-55, 57-62, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpino et al (US 6,110,932 patented August 29, 2000) claiming priority to Provisional Application No. 60/009,469 filed 12/28/95.

Carpino et al disclose a pharmaceutical composition comprising an estrogen agonist/antagonist and an "E series prostaglandin". See column 25, lines 30-44; column 20, lines 7-67, and column 21 lines 1-67. Carpino et al disclose a pharmaceutical composition comprising selecting raloxifene, tamoxifen or idoxifene in combination with a parathyroid hormone or growth hormone. With respect to the "pharmaceutical carrier" described in the instant claims, Carpino et al disclose a pharmaceutical composition comprising the estrogen agonist/antagonist and prostaglandin agonist/antagonist compounds with a pharmaceutical carrier. Regarding the instant "second compound" limitation described in claim 4, 6, 9, 11 and

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33, Carpino et al disclose adding "E series prostaglandin" to a pharmaceutical composition comprising estrogen agonist/antagonist. See the abstract; column 20, lines 46-50; and column 25, lines 30-46. It is noted that "E series prostaglandins" include the selected use of "PGE or PGE as the second compound in the pharmaceutical composition in the instant claims. Also, Carpino et al disclose "a method for the treatment of osteoporosis which comprises administering to a human or other animal with osteoporosis a combination of an estrogen agonist or antagonist such as tamoxifen, droloxifene, raloxifene and idoxifene...". See column 20, lines 46-59 and column 26, lines 1-68. Regarding instant claim limitations reciting "the condition which presents with low bone mass is osteoporosis", Carpino et al disclose a treatment method that uses the composition describe above for treating osteoporosis in a human or other animal in need of this treatment. Further, regarding the "low bone mass" instant limitations, Carpino et al also describe treating humans and animals in need of stimulating osteoblasts, bone remodeling, cartilage growth, inhibiting bone resorption, preventing osteoporosis, stimulating bone formation and increasing bone mineral density. See the abstract; column 20, lines 46-59; column 25, lines 30-46; column 26, lines 1-68; and column

27, lines 1-68. In regards to the instant methods for administering the active compounds and the time periods recited for administration, Carpino et al disclose administering two active compounds in a pharmaceutical combination. Note the abstract. With respect to administering one active compound before administering another active compound as described in the instant claims, it is noted that Carpino et al disclose administering one active compound and optionally adding another active compound before administering to a patient in need. Further, it is noted that Carpino et al disclose administering the active compounds claimed in the instant invention to a human or animal in need of treatment for osteoporosis or related conditions. Note the abstract and column 25, lines 5-67. Thus, Carpino et al disclose or suggest the invention claimed except for describing a kit as claimed.

However, with respect to the instant kit, it is noted that Carpino et al disclosed each of the relevant chemical components in the kit and describe methods for using the components for the same functions set forth in the claims. Carpino et al disclose or suggest all the instant claim limitations except for describing a kit comprising the relevant chemical compounds recited which was deemed to be an obvious modification of the Carpino et

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al invention at the time this invention was made because Carpino et al disclose or suggest each of the relevant chemical components in the kit and describe methods for using the components for the same functions set forth in the claims. It is also noted that skilled artisans would have been required to put the active chemical components described in the instant kit in a container before use in any method. Hence, the Carpino et al reference anticipates or renders obvious the claimed invention.

The burden of proof is on applicants to show patentably distinct differences between the Carpino et al disclosure and the present invention as claimed.

4. Claims 7, 10, 13-29, 48, and 53 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. Applicant's submission of the requirements for the joint research agreement prior art exclusion under 35 U.S.C. 103(c) on 3-15-2005 prompted the new ground(s) of rejection under 37 CFR 1.109(b) presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.02(l)(3). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. The Williams et al reference (American Society of Consultant Pharmacists, pp 1-26, 1996) disclose a pharmaceutical comprising NaF for treating osteoporosis and has been cited to further show the state of this art.

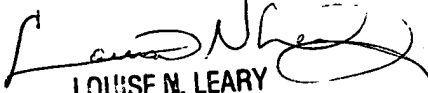
7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise N. Leary whose telephone number is (571) 272-0966. The examiner can normally be reached on Monday to Friday from 9:30 to 6:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campbell, can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



LOUISE N. LEARY  
PRIMARY EXAMINER

March 17, 2005